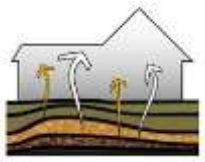
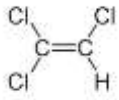
APPROACHES TO MANAGING TCE ACUTE RISKS





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A Perfect Storm Batters Risk Management Decisions for TCE

By David R. Gillay
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EPA's Concern Over TCE Vapor Intrusion Is Misguided

Law360, New York (August, 2014)

Issues

- Cardiac Defects - inconsistent data
- No clear guidance from EPA HQ on implementing RfD for acute exposure
- How short-term is the developmental risk
- How much above RfD is an urgent risk

Outline

- Review of TCE RfD
  - Use of the RfC for Vapor Intrusion
  - Implications of a Developmental RfD for VI
  - Review of the science for TCE
- Federal Approach
  - USEPA HQ
  - USEPA Regions
- Northeast States
- OSHA PEL
- Summary

Use of RfC in Vapor Intrusion

- RfC used to set Target Indoor Air Concs
  - Used to derive soil VC and GW VC
  - Can also be used as indoor air guideline for
    - Evaluating indoor air test results
    - Possible outcomes:
      - Need to continue monitoring
      - Need to remediate
      - Need to warn
      - Need to evacuate
  - RfC becomes a different TAC for residential vs industrial/commercial
    - (24/8* 7/5) to adjust RfC to workplace
  - RfC can be applied to different time frames depending upon endpoint

Implications of a Developmental RfD

- Short term exposures may trigger need to act
  - Unlike most RfDs and cancer targets which assume the need for chronic exposure
- Levels and speed of intervention for TCE VI
  - Cancer-based target: 0.2 ug/m3; may take years to achieve
  - Developmental-based target: 2 ug/m3; days to weeks
- Site-specific considerations
  - Timing of exposure, # and type of occupants; hours/day exposed
  - Just pregnant women or also women of reproductive age?

Basic Elements

- Site presents TCE VI issue due to GW or soil gas
  - What are projected indoor air concs
  - Sampling indoor air
  - If high – intervention steps
    - Immediate sealing and ventilation
    - Potentially warn or evacuation sensitive receptors
    - Longer term sub-slab system or intervention of plume
  - If low – monitor under different IAQ conditions

Basic Elements (cont)

- When, where and how to monitor
  - Triggered by gw or soil gas data
    - Sample locations of at risk workers and likely hot spots
  - Post ventilation sampling
  - Confirmation of long-term fix
  - Field GC could be very helpful

TCE Toxicology
Wt of Evidence on Cardiac Defects

- Rats: two positive studies, two negative studies
  - Positive studies, from one research group, somewhat unusual dose response
- Supported by two positive studies in rats on metabolites
- Supported by chick embryo studies with TCE and metabolites
- Supported by mechanism studies
- Supported by epidemiology studies

TCE Developmental EPI

- Bove et al. 1995, '96, 2002
  - Ecological study - public drinking water and birth outcomes
  - TCE associated with SGA, NTDs, cleft palate, cardiac defects
- ATSDR 2008 Study of TCE VI at Endicott NY
- NRC 2006 Review: *"the epidemiologic studies—although limited individually—as a whole showed relatively consistent elevations for cardiac malformations with similar relative effect sizes of 2- to 3-fold, some of which were statistically significant, associated with TCE exposure across multiple studies."*
- Camp Lejune (Ruckart et al., 2014)
  - TCE associated with SGA and NTDs

Forand et al. 2012 Endicott NY

Figure 1. The TCE and PCE study areas and the location of the former IBM manufacturing facility, Village of Endicott, New York (USA).

- TCE Vapor Migration, no drinking water exposure
- N= approx 2500 in TCE study area
- TCE indoor measurements median = 16 ug/m3, up to 140 ug/m3

Forand et al. Endicott Results

Table 2. Adjusted RRs[a] (95% CIs) for adverse birth outcomes in the PCE, TCE, and combined study areas, Village of Endicott, New York (USA), 1978–2002.

	PCE area		TCE area		Combined study area	
Adverse birth outcome	*n*	RR (95% CI)	*n*	RR (95% CI)	*n*	RR (95% CI)
LBW	12	0.70 (0.39, 1.27)	76	1.36 (1.07, 1.73)*	88	1.20 (0.96, 1.50)
Very LBW	1	0.39 (0.06, 2.78)	14	1.61 (0.94, 2.78)	15	1.32 (0.78, 2.23)
Preterm birth	20	0.74 (0.47, 1.16)	93	1.02 (0.82, 1.27)	113	0.95 (0.79, 1.16)
Very preterm birth	1	0.22 (0.03, 1.58)	20	1.37 (0.87, 2.14)	21	1.09 (0.70, 1.69)
SGA	35	1.04 (0.74, 1.47)	117	1.23 (1.03, 1.48)*	152	1.19 (1.01, 1.39)*
Term LBW	4	0.60 (0.23, 1.60)	37	1.68 (1.20, 2.34)**	41	1.42 (1.04, 1.94)*

[a]Models were adjusted for mother's age, education, race, and number of previous live births; infant's sex; and adequate prenatal care (Kessner index). *$p < 0.05$; **$p < 0.01$.

Table 3. Adjusted RRs[a] (95% CIs) for birth defects in the in the PCE, TCE, and combined study areas, Village of Endicott, New York (USA), 1983–2009.

	PCE area		TCE area		Combined study area	
Birth defect group[b]	*n*	RR (95% CI)	*n*	RR (95% CI)	*n*	RR (95% CI)
All reportable birth defects	17	1.24 (0.75, 2.05)	44	1.07 (0.78, 1.47)	61	1.11 (0.85, 1.45)
Surveillance birth defects	10	1.44 (0.72, 2.88)	25	1.43 (0.96, 2.14)	35	1.43 (1.01, 2.03)*
All cardiac defects	5	1.42 (0.46, 4.39)	15	2.15 (1.27, 3.62)**	20	1.97 (1.22, 3.16)**
Major cardiac defects	2	2.91 (0.73, 11.65)	6	2.40 (1.00, 5.77)*	8	2.53 (1.21, 5.31)*
Conotruncal defects	1	4.91 (0.69, 34.90)	3	4.91 (1.58, 15.24)**	4	4.92 (1.84, 13.11)**

[a]Models were adjusted for the mother's age, education, race, and number of previous live births; infant's sex; and adequate prenatal care (Kessner index). [b]There were no births in the study areas with NTDs, orofacial clefts, or choanal atresia; therefore, these outcomes are not shown. *$p < 0.05$; **$p < 0.01$.

- Higher smoking in study area but not well controlled – LBW, SGA affected in a subanalysis
- Recent meta-analysis: maternal smoking assoc with cardiac defects (Lee and Lupo, 2013)

TCE Developmental Immunotox

- TCE well established as immunotoxicant
  - Impairs some immune functions
  - Stimulates autoimmunity, mice and humans
  - Developing immune system appears sensitive to low level exposure
- TCE RfC equally dependent upon developmental immunotox

Federal Approach: USEPA HQ

- Richardson memo (Aug 2014)
  - Regional Superfund Managers

> Existing guidance provides that responders should consider *early or interim* action(s) where appropriate to eliminate, reduce, or control the hazards posed by a site. In doing so, IRIS generally provides the best available toxicological information in support of *early or interim* action for buildings where investigations of indoor air contamination identify site-related concentrations of TCE.

Region 9 Approach, July 2014

- Rapid intervention to avoid developmental risk
  - Vulnerable period – 3 wks of heart development in first trimester
  - Acute intervention concentrations for residential and industrial/commercial
    - Accelerated vs Urgent Action
  - http://www.epa.gov/region9/superfund/prg/files/r9-tce-interim-action-levels-response-recs-memo-2014.pdf

USEPA Region 9 Numerical Recommendations

EPA Region 9 Interim TCE Indoor Air Response Action Levels - Residential and Commercial TCE Inhalation Exposure from Vapor Intrusion		
Exposure Scenario	*Accelerated Response Action Level (HQ=1)*	*Urgent Response Action Level (HQ=3)*[4]
Residential *	2 µg/m^3	6 µg/m^3
Commercial/Industrial ** (8-hour workday)	8 µg/m^3	24 µg/m^3
Commercial/Industrial ** (10-hour workday)	7 µg/m^3	21 µg/m^3

Accelerated Action: rapid mitigation, sampling confirmation
Urgent Action: immediate cessation of exposure, relocation of workers

USEPA Region 1 Approach

- Site-specific, case-by-case
- Multiple lines of evidence
  - Soil gas, indoor air
- At least one site so far which required more immediate action

USEPA HQ Response to Recent Challenge

- Halogenated Solvents Industry Assoc Challenge to RfC
  - Inappropriate dependence upon Johnson 2003 cardiac defect study
  - Invoked Information Quality Act (IQA)
    - IRIS not being objective, key study not reproducible
- NCEA March 19, 2015 letter strongly defended use of cardiac endpt in RfC
  - HSIA concerns raised during IRIS SAB deliberations
  - RfC relies upon 21 developmental studies, numerous support cardiac endpoint
  - RfC based upon several different candidate endpoints all in same range
  - Addresses details of the Johnson et al. 2003 study (e.g., concurrent controls)

Connecticut Approach, Feb 2015

- Current TAC is 5 ug/m3 – background
- Recognize that development risks in this range
  - 2 ug/m3 – full time exposure, residential
  - 8 ug/m3 – workplace exposure
- If I/C site exceeds limits it is prioritized for immediate followup
  - > 8 ug/m3 indoor air,
  - 1.6 fold greater than GWVC or SVVC, occupational
- Guidance and Toxicology Support Doc on DEEP website: http://www.ct.gov/deep/cwp/view.asp?a=2715&q=560916&deepNav_GID=1626

Connecticut Approach (cont)

- Occupational Alert for female TCE workers
  - Contrasts developmental targets with OSHA PEL
  - Alert for women of reproductive age
  - Provides manufacturers with 9 steps to reduce TCE in workplace including alternative solvents
    - TURI – Lowell Mass

Update TCE MCL

- Federal MCL of 5 ug/L from 1980s
- Several reasons to consider updating
  - New toxicology
  - New detection limits
  - Developmental risk
    - MCL enforcement based upon yearly average of quarterly results
    - A quarter could have **up to 20 ug/L** and still pass
    - This is **4.6 fold above RfD**
  - Lowering MCL to 1 ug/L would address this risk

Massachusetts Approach, Aug 2014

- Mass DEP extensive review of the toxicology
  - Health Effects Advisory Committee
- TCE a developmental toxin with potential to cause cardiac defects
- Cardiac development early before realize pregnant, TCE a concern to early pregnancy and women who may become pregnant
- Cardiac development is completed within the first 8 weeks of pregnancy exposures after that period do not present a risk
- Risk a function of indoor air concentration and exposure duration
- Exposures of a few days to weeks during critical periods of fetal cardiac development of potential concern.

Mass Approach (cont)

- Residential – > 2 ug/m3 – ultimate goal, expeditious achievement
- Residential - > 6 ug/m3 – Imminent Hazard - 2 hr notice to DEP, immediate notification of vulnerable individuals, short-term measures
- Residential - > 20 ug/m3 – More Urgent – consider evacuation of vulnerable individuals
- Occupational > 8 ug/m3 – Expeditious Action;
- Occupational > 24 ug/m3 – Imminent Hazard
- Occupational > 60 ug/m3 – More Urgent

Possible Confusion Across States
What is the immediate response level?

- Mass (Aug 2014): 8 ug/m3 – Expeditious action
  24 ug/m3 - Imminent Hazard
- NH (Feb 2013): 8 ug/m3 – Immediate action, warnings, relocation
- CT (Feb 2015): 8 ug/m3 – Prioritization of site, immed action to ↓ conc
  - CT has no employee warning level
- USEPA Region 9: 8 ug/m3 – Accelerated action;
  24 ug/m3 – Urgent action

Other States in Region

- NYS: draft recommendation
  - immediate action > 20 ug/m3
    - no distinction between resi and I/C
    - In general, endeavor to bring indoor air to background or risk-based goal as quickly as possible regardless of chemical or endpoint
- Maine: Still studying issues
- VT: focus on cancer risk; site-specific consideration of RfD/acute risk
- Rhode Island - In general, endeavor to bring indoor air to background or risk-based goal as quickly as possible regardless of chemical or endpoint

OSHA PEL

- Remains at 100 ppm – 1980s
  - Based upon acute CNS effects, liver and kidney tox
  - Carcinogen status acknowledged
- PEL is 270,000 times > USEPA RfD
  - PEL doesn't apply to general public
    - Vulnerable receptors vs healthy workers, voluntary vs involuntary risk, continuous vs. workplace exposure
  - PEL doesn't apply same risk methodology and level of public health protection as RfD
- ACGIH TLV – lowered to 10 ppm - 2007
  - STEL = 25 ppm
  - TLV basis – CNS effects, renal toxicity
    - Developmental toxicity mentioned briefly
    - Cancer discussed but not part of PEL derivation

Summary

- TCE developmental effects make acute risk more urgent than cancer risk
- Impacts on VI, workplace safety, MCL
- Variety of Responses in Region
  - Numerical guidelines, intervention protocols
  - Case-by-case
  - Still Studying issues
- 8 ug/m3 short-term remediation target
- 24 ug/m3 warning/evacuation target
- Monitor evolving science and reg determinations